REMARKS/ARGUMENTS

Claim status. Claims 2 to 13 and 25 are pending in this application. Claim 25 is amended hereby. Claim 26 has been added.

Claim 26 is intended to correspond to the subject matter deemed allowable by the Examiner (page 9 of the Office Action). The Applicants still wish to pursue the remaining claims and respectfully request consideration of the following remarks.

Objection under Section 132. The Examiner objected that the definition of the X number substituents added by amendment on July 18, 2003 introduced new matter. The Examiner noted that (1) the declaration mentioned therein was not actually filed; (2) the cited US patents did not recite the definitions of the X-numbered substituents as presented in the amended specification. Regarding point (1), a declaration is included with this paper. The Applicants' attorney notes that his file shows that such a declaration was signed and sent with the amendment filed July 18, 2003 but apologizes if by error he failed to include it.

Regarding point (2), the Applicants wish to point out the following concordance between the sequences appearing in the present specification and those of U.S. Pat. No. 5,981,478, which corresponds to WO 95/14714:

Sequence in present spec	Sequence in '478 patent
9	1 (col. 2, lines 1-2)
11	38 (col. 5, line 5)
13	3 (col. 3, line 58)
14	15 (col. 4, lines 59-60)

The foregoing table is meant to convey that SEQ ID NO: 9 of the Applicants' specification is identical to SEQ ID NO: 1 of U.S. Pat. No. 5,981,478 (col. 2, lines 1-2) and so forth for the remaining pairs of sequences aligned by row on the table. SEQ ID NO: 12 is deleted. The Applicants note that the matter added by amendment was specifically rather than generally incorporated by reference. For these reasons, the Applicants respectfully submit that no new matter has been added and request that the objection be withdrawn.

Objection to Sequence Listing. The Examiner noted that the Sequence Listing included only 135 sequences but that Claim 25 recited up to SEQ ID NO: 137. A substitute Sequence Listing is submitted herewith.

Rejection of Claims 2-5, 7-9, 13, and 25 under Section 112, first paragraph and second paragraphs. The Examiner rejected these claims for lack of written description.

The Examiner's argument appears to be that because "some degradation" was noted in the Laminin-5 molecule (defined at page 57, line 5 as a five-time tandem repeat of the peptide YIGSR), there is no written description of "molecules that can be fused to the Fc region without being degraded by proteolytic enzymes" (Office Action at page 4). The Examiner then alleged that only those peptides designed to avoid degradation (SEQ ID NOS: 95 and 96) are enabled (Office Action at page 5).

In an argument styled as a written description rejection, the Examiner actually imposes a specific burden of utility beyond that of Section 101. The patent statute only requires that the claimed compounds be *useful*, not that they avoid degradation. Any active molecule satisfies the utility requirement, whether or not that molecule undergoes degradation. Example 3 of the specification notes that the laminin-5 molecule underwent "some protoeolysis" but it also states that laminin-5 is active; the specification notes that the IC100 was hard to assess *accurately* due to heterogeneity, but it does indicate that the molecule had activity in the assay. Indeed, the specification indicates that the degradation products, which maintained the laminin sequence (YIGSR, SEQ ID NO: 7), are active (page 57, lines 11-12). The Examiner is asked to consider that widely marketed pharmaceuticals such as Seldane® and Claritin® were later found to be pro-drugs having active metabolites. Such molecules were still useful, as demonstrated by their years in use.

The Examiner's rejection also interprets the degradation of the laminin-5 molecule as leaving skilled artisans with "no guidance as to which adhesion molecules can be attached to Fc such that degradation would not occur." (Office Action at page 5). Again, the Examiner imposes a duty of utility beyond that of Section 101--the molecules claimed are useful because they are active, even if a molecule that avoids degradation would be more desirable. Moreover, contrary to the Examiner's assertion, the specification actually describes the degradation products in the same passage cited above (page 57, lines 11-12). The degradation products maintain at least one laminin (SEQ ID NO: 7) repeat and, as noted, appear to be active. Thus, the activity of the degradation products is consistent with the activity of the laminin-3 Fc fusion molecule, which showed a 50-fold improvement over the laminin-3 peptide without Fc fusion (page 57, line 8). In addition, no degradation was noted for the laminin-3 peptide nor the laminin-3 Fc fusion, which had IC100's of 2.9 μM and 55 nM, respectively (Specification at page 57, lines 7-9). Thus, the skilled artisan *is* given guidance regarding the presence of the laminin peptide. Furthermore, that guidance is consistent with Claim 2, which requires at least one laminin (SEQ ID NO: 7) peptide.

The Examiner also contends that the specification as filed does not support the presently claimed proviso that at least one of the P comprises SEQ ID NO: 7. Claim 2 as amended, however, is fully encompassed within Claim 12 as originally filed, which required "one or more sequences selected from SEQ ID

NOS: 7 and 9 to 16." Furthermore, one of the priority documents, 60/198,919, filed April 21, 2000, was directed toward molecules as claimed in amended Claim 2.

Rejection of Claim 13 under Section 112, second paragraph. Claim 13 was rejected for its reference to tables appearing in the specification. Although the Applicants perceive no indefiniteness and hereby explicitly do not admit to any indefiniteness, the Applicants hereby amend Claim 13 to accommodate the Examiner.

Rejection of Claim 25 under Section 112, second paragraph. The Applicants thank the Examiner for reconsidering the Section 112, second paragraph rejections to Claim 2-5, 7-9, 13 and 25. The Examiner rejected amended Claim 25 for including SEQ ID NO: 132, which did not include SEQ ID NO: 7 as required in its antecedent claim. The Applicants hereby amend Claim 25 to obviate this ground for rejection.

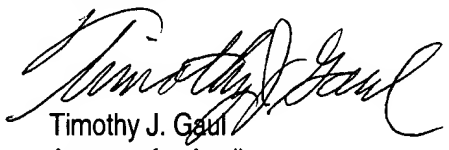
Rejection under Section 103. The Examiner rejected Claims 2-5, 7-9, 13, and 25 under Section 103 over Whitty *et al.* (US Pat. Appl. 2002/015547) in view of Mu *et al.* (1999), *Biochem. Biophys. Res. Comm.* **255**: 75-9.

The Examiner maintains this rejection without showing why a cytokine as taught by Whitty et al. would be predictive of success with the laminin pentapeptide. The small size of the laminin pentapeptide alone gives it a significant structural difference with interferon beta and other molecules that have been linked to Fc domains. The Examiner further fails to point to any suggestion to combine the teachings of the two references, relying instead on a hindsight reconstruction using the application itself as a guide. Furthermore, the Examiner is asked to consider that the prior art does not predict the results noted above--an improvement in activity from the low micromolar range to the low nanomolar range when coupled to Fc (page 57, lines 7 to 9).

For these reasons, the Applicants respectfully submit that there is no suggestion in the art to combine the teachings of Mu *et al.* and Whitty *et al.* and that their teachings, even in combination, fail to encompass the claimed invention.

Conclusion. In view of the foregoing amendments and remarks, the Applicants respectfully request reconsideration of the restriction requirement, entry of all amendments, and allowance of all claims.

Respectfully submitted,



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